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EXAMINER

PREBILIC, PAUL B

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 45

Application Number: 09/014,087
Filing Date: January 27, 1998
Appellant(s): CARLYLE ET AL.

MAILED
SEP 8 2003
GROUP 3700

Iain A. McIntyre
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 23, 2003.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is substantially correct. The last sentence of Section III in the Appeal Brief give the current status of the present claims except that claims 3, 12, 13, and 16-20 have been cancelled not withdrawn by previous amendments.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. To be more concise, all amendments have been entered including the after final amendment filed February 3, 2003.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is substantially correct. However, the Examiner would substitute the word "unpatentable" for the word "rejected" for each of the first lines of each issue.

In addition, the 35 USC 103(a) portion of Issue B has been withdrawn as of the date of this Examiner's Answer.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 2, 4, 5, 9-11 and 29 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8). It is noted that only claim 29 is argued separately. All the other claims of record stand or fall with the particular rejection that they are linked. In addition, it may have been more appropriate to use the "Group" instead of "Issue" in this section of the Appeal Brief because there are only 5 issues listed in the issues section A to E. However, there are six "Issues" in this section A to F.

(8) Claims Appealed

A substantially correct copy of appealed claims 1, 2, 4-11, 14, 15, and 21-29 appears on pages 18-21 of the Appendix to the appellant's brief. The minor errors are as follows:

In claim 15, on line 2, the phrase "or bovine" should be inserted after "porcine."

(9) Prior Art of Record

5,631,011	Wadstrom	5-1997
5,308,641	Cahalan et al	5-1994
4,648,881	Carpentier et al	3-1987
EP 0476983 A1	Bayne et al	3-1992

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(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6, 9-11, 14, and 21-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8-11, 13, 15, and 34-40 of copending Application No. 09/186,810.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the copending claims is so similar to the present claimed subject matter that the claim sets read on each other such that they are at least clearly obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan (US 5,308,641). Cahalan anticipates the claim language wherein the human or animal tissue is used as the solid surface and the biomolecule is one of the growth factors listed on column 6, lines 14-18; also see the abstract, column 4, lines 20-43, and column 6, lines 8-28. It is noted that "fixed" and "crosslinked" are synonymous in the tissue graft implant art. Furthermore, glutaraldehyde is disclosed as one of the crosslinking agents of Cahalan; see column 4, lines 58-62.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayne et al (EP 0476983), or alternatively, under 35 USC 103(a) as being unpatentable over Bayne et al alone wherein the fibrin coating is applied prior to or in addition to the VEGF II growth factors to the surface of the fixed umbilical cord vein; see the abstract,

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page 8, lines 14-26, and in particular, page 8, lines 20-23. The Examiner posits that the tubular supports coated with VEGF II include fixed umbilical cord vein, and thus, the claim language is fully met.

Alternatively, if one does not consider the tubular supports coated with VEGF II as including umbilical cord vein, then the claim language is not fully met. However, the Examiner posits that it would have been clearly obvious to use umbilical cord vein as the tubular support since it is used as an implant in another procedure it would bring the desired features of tissue properties to the implant site.

Claims 1-2, 4-5, 9-11, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al (EP 0476893) in view of Wadstrom (US 5,631,011). Bayne et al discloses an implant having a fibrin coating (a biologic adhesive as claimed), which is applied prior to the VEGF II growth factor (VEGF II is the polypeptide growth factor as claimed). The fixed umbilical cord vein of Bayne et al is the substrate for coating as claimed; see page 8, lines 14-26. However, the Bayne et al cord vein, although a crosslinked human or animal tissue, is not clearly either an allograft or xenograft as claimed. Nonetheless, it is the Examiner's position that it would have been considered clearly obvious to an ordinary artisan to use an allograft or xenograft tissue for the cord vein of Bayne et al absent some showing of criticality therefor.

Wadstrom is cited to show that fibrin is a common biologic tissue adhesive in the art (see the abstract and column 1, lines 1-20), and thus, the fibrin coating of Bayne et al can be called and would function as a biologic adhesive as claimed.

Claims 6-8, 14, 15, 21-24, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bayne et al and Wadstrom as applied to claims 1-5, 9-11, and 29 above, and further in view of Carpentier (US 4,648,881). Bayne et al fails to disclose uncrosslinked tissue, the heart valve form of the tissue, or the other tissue types as claimed. However, Carpentier teaches that all uncrosslinked and crosslinked forms of tissue, heart valve tissue forms and other types of tissue are all well known in the art; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use any of these materials as the substrate of Bayne et al for the applications contemplated by Carpentier. One would be motivated to form Bayne et al implants into other shapes in order to make it useful in other sites and broaden its applicability.

(11) *Response to Argument*

First, the Examiner would like to point out a couple of typographical errors in the corresponding section of the Appeal Brief. On page 14 of the Appeal Brief, the subheading "Issue F" should read "Issue E" in order to correspond to the language in the Group of Claims section. Similarly, on page 16 of the Appeal Brief, the subheading "Issue G" should read "Issue F" to correspond to the language of the Grouping of Claims section.

ISSUE A

Appellants point out some differences between the corresponding claim sets of the present claims and the copending claims, but Appellants fail to point out why the claim sets are patentably distinct. For this reason, the Examiner asserts that the claim sets are obvious in view of each other.

It is noted that Appellants have offered to file a terminal disclaimer if the claims are allowed.

ISSUE B

Appellants argue that "crosslinked" is different from "partially crosslinked or lightly crosslinked" because it denotes complete crosslinking; see page line 9, second full paragraph of the Brief. However, the Examiner asserts that "lightly crosslinked" is read on by "crosslinked" because lightly crosslinking is a type or degree of crosslinking. For this reason, the claim language is fully met because "lightly crosslinked" falls within the scope of "crosslinked."

ISSUE C

Appellants argue that the fixed umbilical vein of Bayne is not coated with fibrin and the VEGF II agent; see page 12 of the Appeal Brief. In response, the Examiner asserts that the "artificial blood vessels", "polymeric blood vessel", and "artificial vessel" are referring to the "fixed umbilical vein" of Bayne; see page 8, line 19 of Bayne. This interpretation is also made in this way because "fixed umbilical vein" is the only type of artificial vessel set forth in this paragraph of Bayne's disclosure. For this reason, the Examiner asserts that the claim language is fully met.

Even if the Board does not agree with the Examiner's interpretation, it is urged that they seriously consider affirming the 35 USC 103(a) portion of the rejection. This is due to the fact that Bayne is quite broad in his application of vascular endothelial cell growth factor II. For example, it is disclosed for use as a medicament (see claim 14), as a treatment for synthetic polymeric vessels (see *supra* and claims 16 and 17), and for

use in vascular repair (see claim 17 and page 8, lines 27-37). For these reason, the Examiner asserts that it would have been clearly obvious to use this growth factor on fixed umbilical vein.

ISSUE D

In response to the Appellants' traversal that Bayne does not disclose growth factor and fibrin with umbilical vein, the Examiner asserts that both of these are suggested by Bayne for the reasons set forth earlier. Furthermore, Wadstrom is used to show that fibrin is known as an adhesive in the art; see column 1, lines 18-21. It is noted also that Appellants are attacking Wadstrom individually and not treating it as the teaching reference it is.

Next, Appellants argue that Wadstrom is to an "anti-adherence composition." However, upon review of Wadstrom, it was determined that the anti-adherence composition is a different and distinct embodiment than that relied upon by the Examiner; see column 3, lines 24-30 and column 6, lines 46-58.

Appellants argue that fibrin is not an adhesive only the precursors of fibrin are; see page 14 of the Appeal Brief. However, the Appellants' own specification states that fibrin is a type of adhesive; see page 13, lines 15-20 of the present specification. Additionally, Bayne teaches that fibrin and other proteins "enhance attachment of cells to the artificial surface"; see page 8, lines 21-23. Moreover, Wadstrom teaches that fibrin is a biological adhesive; see *supra*. For these reasons, the Examiner asserts that fibrin is an adhesive to the extent that this language can be given patentable weight.

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ISSUE F (should be "E").

Appellants use many of the same arguments against claim 29 as those used against the other claims of the same rejection so the Examiner will not represent those responses here.

In response to the argument that there is no motivation to combine Wadstrom with Bayne, the Examiner asserts that the reason for the combination is merely to show that the properties of fibrin as an adhesive in the art was well known. Furthermore, since Wadstrom is in the same art of vascular tissue repair as that of Bayne, the Examiner asserts that the motivation for relying on Wadstrom is the same as the reason Wadstrom uses the same material in the art.

ISSUE G (should be "F")

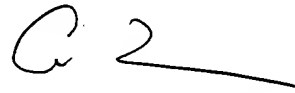
In response to the traversal that there is no motivation to combine Carpentier with Bayne, the Examiner notes that the motivation is clearly set forth in the rejection as "[o]ne would be motivated to form Bayne et al implants into other shapes in order to make it useful in other sites and broaden its applicability." Furthermore, Bayne is drawn to all types of vascular tissue repair. Carpentier is directed to specific repair of, preferably, tissue heart valves. Tissue heart valves are types of vascular grafts. For this reason, one in the art would clearly look to Carpentier to see some specific uses of the tissue repair composition of Bayne.

For the above reasons, it is believed that the rejections should be sustained.

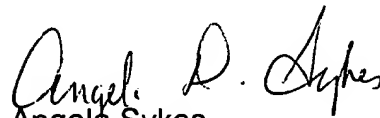
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